IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
Houston Division

NATURAL ALTERNATIVES INTERNATIONAL, INC., Plaintiff, v. WOODBOLT DISTRIBUTION, LLC, *et al.*, Defendants.	)	Civil Action No. 11-4511

PLAINTIFF NATURAL ALTERNATIVES INTERNATIONAL, INC.'S MEMORANDUM IN OPPOSITION TO DEFENDANT WOODBOLT'S MOTION FOR SUMMARY JUDGMENT OF PATENT INVALIDITY AND IN SUPPORT OF ITS CROSS MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT BY WOODBOLT AND THAT THE PATENTS-IN-SUIT ARE NOT INVALID

Richard J. Oparil
S.D. Texas Bar No. 30422
Kevin M. Bell
Scott Chambers, Ph.D.
Lacy Kolo, Ph.D.
PATTON BOGGS LLP
2550 M Street, NW
Washington, DC 20037
(202) 457-6000
roparil@pattonboggs.com

Dated: August 17, 2012

Glenn A. Ballard, Jr.
State Bar No. 01650200
BRACEWELL & GUILIANI
South Tower Pennzoil Place
711 Louisiana, Suite 2300
(713) 223-2300
(713) 221-1212 (fax)

Caroline Cook Maxwell
State Bar No. 24055341
S.D. Texas Bar No. 927197
PATTON BOGGS LLP
2000 McKinney Avenue, Suite 1700
Dallas, TX 75201
(214) 758-1500

Attorneys for Plaintiff
Natural Alternatives International, Inc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

OTHER AUTHORITIES

INTRODUCTION

Plaintiff, Natural Alternatives International, Inc. ("NAI"), opposes the motion for summary judgment of invalidity under 35 U.S.C. §§ 102 and 103 filed by defendant, Woodbolt Distribution, LLC (d/b/a Woodbolt International and Cellucor) ("Woodbolt") (Dkt. No. 53), and cross moves for summary judgment of infringement of one or more claims of NAI's U.S. Patent Nos. 8,067,381 ("the '381 patent") (Ex. 1) and 8,129,422 ("the '422 patent") (Ex. 2) and that both patents are not invalid.

Woodbolt's accused products infringe valid claims of the patents-in-suit. After being given multiple opportunities to come forward, Woodbolt was unable to raise a non-infringement defense in response to the evidence in NAI's preliminary injunction motion (Dkt. No. 10; C.A. No. 12-1388 Dkt. No. 14), and it chose not to move for summary judgment of non-infringement pursuant to the Court's July 23, 2012 Management Order (Dkt. No. 49). Also, the stipulation Woodbolt filed with the Court (Dkt. No. 52), raises no non-infringement defense, but instead bolsters NAI's infringement contentions. Woodbolt has thus waived any non-infringement defense and has conceded the accused products are covered by claims of the patents-in-suit. NAI respectfully requests this Court grant its cross motion for summary judgment of infringement of claims 1, 11 and 13 of the '318 patent and claims 12, 14, 16, 17 and 19 of the '422 patent the accused products.

Woodbolt has failed to prove by clear and convincing evidence that the patents-in-suit are invalid pursuant to 35 U.S.C. §§ 102 and 103. Woodbolt's motion did not come forward with any prior art references that teach all of the necessary claim limitations or even inherently lead to these limitations. Specifically, none of the references cited by Woodbolt in support of its § 102 invalidity assertions contain all of the limitations of the patents-in-suit in a single reference. Further, no combination of the cited references support any of Woodbolt's §103 assertions.

Woodbolt's invalidity arguments are based on an incomplete and erroneous construction of the claim terms of the '381 and '422 patents and scientific theories that are not supported by actual record evidence. It even tries to reassert prior art that NAI expressly disclaimed during prosecution and recommends this Court simply adopt and give binding effect to a claim construction from a different case in a different Court involving different parties and different patents.

Additionally, Woodbolt's assertion that NAI's own U.S. patent number 5,965,596 invalidates the patents-in-suit due to an alleged "break" in the chain of priority is simply wrong as a matter of law. Woodbolt admits in its opening brief that NAI has complied with the relevant statute relating to its priority claim, 35 U.S.C § 120. It then tries to complicate a simple issue – were two patent applications co-pending on August 29, 2008? They were, and there was no purported "break" in priority, thus nullifying Woodbolt's assertion of invalidity based on the '596 patent.

Finally, in line with its repeated attempt to delay its day of reckoning with NAI, Woodbolt's motion provides a "status update" of its *inter partes* reexamination proceeding, followed by a renewed request for reconsideration of its July 23 request to the Court that the U.S. Patent and Trademark Office ("PTO") be allowed to take the lead, even though it will take years to complete that administrative proceeding. Ironically, this is the same government agency that Woodbolt claims did such a poor job in issuing the patents-in-suit in November 2011 and March 2012, but is now claiming it to be the preferred venue to take a second look at those patents just months later. Moreover, Woodbolt's argument that this Court should simply adopt the preliminary reexamination ruling made by the Examiner – who, to date, only has Woodbolt's argument to review without any comment from NAI – is contrary to law and invites error.

Therefore, NAI respectfully submits that the Court deny Woodbolt's motion for summary judgment of invalidity and grant NAI's cross motion that the patents-in-suit are infringed and are not invalid.

BACKGROUND

NAI is a publicly traded formulator, manufacturer and marketer of nutritional supplements and provides strategic partnering services to its customers. (Dkt. No. 1 ¶ 1, 7; C.A. No. 12-1388 Dkt. No. 14-2 ¶¶ 3, 4). NAI owns the '381 patent, issued November 29, 2011, and the '422 patent, issued March 6, 2012. Both patents are entitled "Methods and compositions for increasing the anaerobic working capacity in tissues." (Exs. 1-2). Prior to the pioneering work of the inventors, products available to counteract the onset of fatigue from high intensity and prolonged exercise were of limited value. The inventors' research demonstrated that these earlier products and their use were inefficient and did not lead to the increased muscular performance provided by beta-alanine.

While performing research on the physiology of muscles and how muscles work, Drs. Roger Harris and Mark Dunnett, the co-inventors on the patents-in-suit, discovered that a particular dipeptide, beta-alanylhistidine (also known as carnosine), was particularly useful to counteract fatigue, and its concentration in muscles could be increased by providing the single amino acid beta-alanine. (Ex. 1 col. 8 l. 49-col. 9 l. 13). Beta-alanine and the amino acid L-histidine are covalently joined by an enzyme to form beta-alanylhistidine. (*Id.*). While beta-alanine is a naturally occurring amino acid, it is not one of the 20 common amino acids found in proteins. Drs. Harris and Dunnett discovered that they could regulate hydronium ion concentrations in human muscle by providing beta-alanine as a supplement. Importantly, increasing the amount of beta-alanylhistidine in the muscle cells increases the cell's ability to

function with insufficient amounts of oxygen, *i.e.*, under anaerobic conditions, thereby limiting muscle fatigue and soreness. (*Id.*).

The inventors' work made beta-alanine a valuable addition to the sports supplement market and its usage has greatly expanded since the inventions. (Dkt. No. 14-2 ¶ 11). The inventions have garnered commercial success in the field of sports nutrition. For example, during the nine months ended March 31, 2012, NAI's royalty revenue from sales of CarnoSyn® beta-alanine by its authorized distributor totaled $4.1 million. (*Id*. ¶ 15; C.A. No. 12-1388, Dkt. No. 14, Ex. 22 at 15).

Defendant Woodbolt offers for sale and sells sports nutrition supplements, including C4 Extreme, M5 Extreme, and N-Zero Extreme (collectively, "the Accused Products"), which contain beta-alanine and provides instructions for their use. (Ex. 1; Dkt. No. 10; C.A. No. 12-1388 Dkt. No. 14). As further discussed below, Woodbolt has never proffered a non-infringement theory related to the '381 and '422 patents, let alone any facts that might support such a defense. Instead, Woodbolt continues to knowingly infringe NAI's valid patents.

ARGUMENT

I. NAI'S UNCONTESTED CROSS MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT SHOULD BE GRANTED.

NAI cross moves for partial summary judgment against Woodbolt for infringing claims of the patents-in-suit. NAI's preliminary injunction motions and accompanying declarations and evidence, incorporated herein by reference, established both factually and legally that the Accused Products infringe at least claims 1, 11 and 13 of the '381 patent and at least claims 12, 14, 16, 17 and 19 of the '422 patent. (Dkt. No. 10; C.A. No. 12-1388 Dkt. No. 14). Woodbolt responded to NAI's motion on the '422 patent but did not raise any non-infringement defense. (Dkt. No. 43). *Elrod v. Burns*, 427 U.S. 347, 350 n.1 (1976) (uncontroverted affidavits filed in

support of motion for preliminary injunction taken as true); *Bradley v. Pittsburgh Bd. Of Educ*., 910 F.2d 1172, 1175-76 (3d Cir. 1990) (finding no hearing necessary on preliminary injunction motion where facts in affidavits and other documentary evidence are undisputed). Woodbolt did not submit a response to NAI's motion for preliminary injunction related to infringement of the '381 patent. (Dkt. No. 10).

At the July 23, 2012, pre-trial conference with the Court, Woodbolt refused to stipulate to infringement of the patents-in-suit. (Dkt. No. 56 at 22). The Court's July 23, 2012, Management Order required Woodbolt to file a stipulation setting forth in detail what it makes, how it makes it, and what it is used for; the stipulation was to be "factual" and be without "abstractions." (Dkt. Nos. 49 & 56 at 28). The bare bones stipulation that Woodbolt filed did not contain any facts or argument supporting a non-infringement position. (Dkt. No. 52). To the contrary, the stipulation further supported NAI's allegations of infringement. Woodbolt's answer to the infringement allegations in NAI's complaints were conclusory and alleged no factual or legal basis for any non-infringement defense. (Dkt. Nos. 50, 51). Finally, the Court's Management Order stated that "Woodbolt must move for summary judgment on invalidity and non-infringement of the patents." (Dkt. No. 49). Woodbolt chose not to file a motion regarding non-infringement, instead limiting its motion to invalidity arguments under §§ 102 and 103.

The Court has afforded Woodbolt at least five opportunities to present a non-infringement defense. In each instance, Woodbolt chose not to do so. The only facts of record show infringement of '381 and '422 patent claims through Woodbolt's offer for sale and sale of its C4 Extreme, M5 Extreme and N-Zero Extreme products containing beta-alanine. Attached as Ex. 3 is a claim chart that, based on the evidence previously submitted to the Court and Woodbolt's stipulation, proves that Woodbolt infringes the patents-in-suit. As such, NAI

respectfully requests the Court to grant its cross motion for summary judgment of infringement of claims 1, 11 and 13 of the '381 patent and claims 12, 14, 16, 17 and 19 of the '422 patent.

II. WOODBOLT'S PROPOSED CONSTRUCTIONS OF THE CLAIMS OF THE '381 AND '422 PATENTS ARE INCOMPLETE AND ERRONEOUS.

To address Woodbolt's invalidity argument, certain terms of the patents-in-suit require construction.

A. The Term "Human Dietary Supplement" Should Be Construed As A Claim Limitation In The '381 Patent.

1. Woodbolt Agrees That The Term "Human Dietary Supplement" Is A Claim Limitation And Should Be Given The Meaning Given To It By NAI In The Prosecution History Of The '381 Patent.

Claim 1 of the '381 patent is an independent claim, and dependent claims 2-14 include further limitations of claim 1. Claim 1 is directed to:

> A human dietary supplement comprising at least one of: an amino acid wherein said amino acid is beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide; an ester of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide; or an amide of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide.

(Ex. 1). Woodbolt agrees with NAI that the claim covers beta-alanine in the form of a single amino acid and that the amide and ester portions of the claim are not relevant in this case. (Dkt. No. 53 at 8). Woodbolt also agrees that the term "human dietary supplement" should be considered a claim limitation, telling the Court:

> Woodbolt agrees – for the purposes of this motion only – to consider the term "dietary supplement" to be a claim limitation, and further agrees – for the purposes of this motion only – to give the preamble term "dietary supplement" the meaning given to it by NAI during the prosecution of the '381 and '422 Patents.

(Dkt. No. 53 at 7). Both parties, therefore, agree that "human dietary supplement" is a claim limitation and that the plain meaning of the term is the same as NAI expressly defined it in the

prosecution history of the '381 patent.[1] Woodbolt quotes NAI's First Preliminary Amendment to the patent application that led to the '381 patent, which clearly and unambiguously informed the Examiner what the claim term meant and did not mean:

> By human dietary supplements the applicants mean an addition to the human diet in a pill, capsule, tablet, powder, or liquid form, which is not a natural or conventional food, and which effectively increases the function of tissues when consumed. . . . To be clear, the term "human dietary supplement", as claimed, does not encompass, and does not mean, a natural or conventional food, such as chicken or chicken broth, for example.

(Dkt. No. 53 at 7, quoting Ex. 4 at 5). Thus, Woodbolt agrees with NAI that "human dietary supplement" should be construed as an addition to the human diet,[2] ingested as a pill, capsule, tablet, powder or liquid, which is not a natural or conventional food[3] that increases the function of tissues when consumed.[4]

---

[1] As discussed below, NAI's cross motion seeks an affirmative ruling from the Court that the term "human dietary supplement" is a claim limitation in the '381 patent claims.

[2] The definition submitted by the applicants in the First Preliminary Amendment (Ex. 4) and accepted by the Examiner is consistent with the definition of the term provided under the Dietary Supplement Health and Education Act of 1994 (DSHEA), which defines dietary supplement as "a product … intended to supplement the diet…." 21 U.S.C. § 321(ff)(1). It is also consistent with dictionary definitions of the term. *See, e.g.*, AMERICAN HERITAGE® NEW DICTIONARY OF CULTURAL LITERACY, THIRD EDITION, Houghton Mifflin Company, 2005 ("dietary supplement" is "[T]he wide assortment of minerals, vitamins, and sundry herbs that are taken as nutritional supplements to regular food.") (Ex. 5). Thus, any argument by Woodbolt in its brief that claim 1 encompasses anything that can be taken into the human body is overbroad, inconsistent with the meaning given to "human dietary supplement" by NAI during prosecution, and contrary to Woodbolt's stipulation agreeing to NAI's definition. (Dkt. No. 53 at 7).

[3] The First Preliminary Amendment expressly stated that the term "human dietary supplement" was "not a natural or conventional food." (Ex. 4 at 6). It also expressly disclaimed that the claims covered "beef, pork, chicken, meat extract supplements and predigested meat/protein supplements" or "other naturally occurring compositions." (*Id*.). That Amendment also referred to interrogatory responses by a defendant, Vital Pharmaceuticals ("VPX"), in a prior case in U.S. District Court for the District of Delaware involving three different NAI beta-alanine patents. NAI submitted VPX's interrogatory responses to the PTO and expressly disclaimed VPX's arguments set forth therein, including any claim to meat and food flavorings. (Exs. 4, 6, 7). This portion of NAI's definition is also consistent with DSHEA, which provides

In addition, acting as their own lexicographers, the applicants made clear that "human dietary supplements" did not include pharmaceutical products. "A claim must be read in view of the specification of which it is a part." *Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp.*, 55 F. 3d 615, 621 (Fed. Cir. 1995). The patent specification distinguished between dietary supplements and pharmaceutical compositions -- the composition "can be used for the preparation of a dietary supplement (including, e.g., drinks, gels, foods) **or** pharmaceutical composition for humans or animals." (Ex. 1 col. 5 ll. 14-17, emphasis added). "Canons of construction ordinarily suggest that terms connected by a disjunctive be given separate meanings, unless the context dictates otherwise…." *Reiter v. Sonotone Corp*., 442 US 330, 339 (1979). Thus, the applicants intended that pharmaceutical products were not to be included in the definition of "human dietary supplement" as claimed in the '381 patent.[5] Woodbolt's suggestion that the claims of the '381 patent covers pharmaceutical products intended to treat or cure a disease is contradicted by the specification, the prosecution history and Woodbolt's agreement to stipulate to the meaning given by NAI to the term "human dietary supplement."

Notwithstanding its representation to the Court and NAI that it will treat the term "human dietary supplement" as a claim limitation in the '381 patent as it is defined in the prosecution history, Woodbolt's proposed claim construction utterly fails to give the term any meaning. Instead, Woodbolt suggests to the Court that "human dietary supplement" could be **any** composition that a human could ingest. This ignores the ordinary meaning of the term, the

---

that a dietary supplement is something that "is not represented for use as a conventional food." 21 U.S.C. § 321(ff) (2)(B).

[4] Because Woodbolt has admitted that, for purposes of this motion, "human dietary supplement" is a claim limitation as defined in the prosecution history, its reference to the DeLacharriere patents on wrinkle cream is baseless; wrinkle cream is not a dietary supplement.

[5] A dietary supplement is not a drug. 21 U.S.C. § 321(ff)(3).

prosecution history of the '381 patent and Woodbolt's express stipulation to apply the meaning of the term as defined by NAI.

Thus, in light of its plain and ordinary meaning and as set forth in the prosecution history and agreed to by Woodbolt, claim 1 of the '381 patent should be construed to read: "A human dietary supplement – meaning an addition to the human diet in a pill, capsule, tablet, powder, or liquid form for effectively increasing the function of tissues when consumed, where the addition is not a natural or conventional food, meat or food flavoring, and is not a pharmaceutical product – comprising beta-alanine as a single amino acid, unbonded to a different amino acid." Properly construed, only prior art that discloses a "human dietary supplement," as defined herein, comprising beta-alanine as a single amino acid would be relevant to Woodbolt's invalidity contentions regarding claim 1 of the '381 patent.

Woodbolt's claim construction argument ignored the dependent claims of the '381 patent (2-14), which add further limitations to claim 1. Most relevant here is claim 13, which further limits the human dietary supplement to one where the supplement is effective in delaying the onset of fatigue in a human. (Ex. 1 col. 7 ll. 5-9). According to the '381 patent, increasing the amount of "beta-alanylhistidine dipeptides in the muscles can increase the tolerance of the cells to an increase in hydronium ion production with anaerobic work and lead to an increase in endurance during exercise before the onset of fatigue." (Ex. 1 col. 6 ll. 62-66). Thus, claim 13 requires the human dietary supplement to be present in a sufficient amount that it will increase the amount of beta-alanylhistidine dipeptides in the muscles and delay the onset of fatigue.[6]

[6] Claim 2 adds a further requirement to the human dietary supplement of claim 1, that it contain a carbohydrate in addition to beta alanine. Claims 3 and 4 require more specific types of carbohydrates. Claim 5 requires that an additional amino acid, L-Histidine be present in the human dietary supplement. *See Electro Scientific Indus, Inc. v. Dynamic Details, Inc*., 307 F.3d 1343, 1348 (Fed Cir. 2002) (finding the preamble to be a limitation because references in the rest

2. The Court Should Affirmatively Construe The Preamble Term "Human Dietary Supplement" As A Claim Limitation In The '381 Patent.

Because Woodbolt has agreed that only for purposes of its summary judgment motion, the Court should construe the term "human dietary supplement" as a claim limitation and give it the meaning given to it by NAI during prosecution. (Dkt. No. 53 at 8). NAI respectfully requests that the Court affirmatively construe the "human dietary supplement" preamble term to be a limitation for the claims of the '381 patent as a matter of law.[7]

Whether to treat a preamble as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention described. *See Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.,* 289 F.3d 801, 808 (Fed. Cir. 2002). "[T]he preamble is analyzed to ascertain whether it states a necessary and defining aspect of the invention, or is simply an introduction to the general field of the claim." *On Demand Mach. Corp. v. Ingram Indus.,* 442 F.3d 1331, 1343 (Fed. Cir. 2006). Further, "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." *Catalina Mktg.*, 289 F.3d at 808, *Computer Docking Station Corp v. Dell, Inc.,* 519

---

of the claim "derive antecedent basis from this preamble language"); *Bell Commc'ns,* 55 F.3d at 620 (accord). Claims 6 and 7 require the addition of insulin or an insulin stimulating agent to the human dietary supplement. Claims 8 and 9 require the addition of creatine or certain forms of creatine to the human dietary supplement. Claims 10 and 11 require that the human dietary supplement be in liquid and solid form, respectively; and claim 12 is directed to a human dietary supplement in an ingestible suspension. Importantly, claims 10-14 reference the human dietary supplement mentioned earlier in the claim, once again supporting the fact that the term human dietary supplement must be a limitation. *Id.* at 1348; *Rapoport v. Dement,* 254 F.3d 1053, 1059 (Fed. Cir. 2001). Finally, claim 14 further limits the human dietary supplement to one where the supplement is effective in protecting the function of a creatine-phosphorylcreatine system.

[7] The preamble issue only implicates claims 1-12 of the '381 patent. There is no preamble issue related to the '422 patent and Woodbolt cannot suggest otherwise.

F.3d 1366, 1375 (Fed. Cir. 2008) (statements made during prosecution can require a term in the preamble to limit a claim).

The intrinsic evidence demonstrates that the preamble of claim 1 of the '381 patent is limiting. NAI's overall *claim structure* is simple with an emphasis on the preamble for defining the invention as a "human dietary supplement." There is a strong prevalence of the use of supplements throughout the claims and specification of the '381 patent.[8] Claim 1's preamble provides an *antecedent basis* to limitations in subsequent dependent claims 2-14. *Electro Scientific Indus.,* 307 F.3d at 1348; *Bell Commc'ns,* 55 F.3d at 620.

The prosecution history of the '381 patent erases any doubt on the question. Woodbolt's own motion quotes NAI's First Preliminary Amendment, which is replete with statements that "human dietary supplement" is a claim limitation. NAI told the Examiner that "the **claims encompass human dietary supplements**." (Ex. 4 at 5, emphasis added; *see also id.* at 4 ("The claims encompass human dietary supplements"); *id.* at 5 ("the use of beta-alanine in a human dietary supplement is not disclosed by" a prior art reference cited to the PTO). After reviewing NAI's First Preliminary Amendment, the Examiner allowed the '381 patent to issue. (Ex. 8). Thus, the clear and unambiguous prosecution history establishes that the preamble should be construed as a limitation.

B. Woodbolt's Proposed Rewrite Of Claim 12 And The Dependent Claims Of The '422 Patent Disregards Important Claim Terms And Should Be Rejected.

In the guise of construing claims, Woodbolt improperly asks the Court to adopt its allegedly "simplified" version of claim 12 of the '422 patent (and their dependent claims). Woodbolt's suggestion that claim 12 should be construed as the mere "use of beta-alanine as a

[8] *See, e.g.*, Ex. 1 col. 1:40-47; col. 4:55-58; col. 5:46-52; col. 6:53-54; col. 9:50-61; col. 10:38-63; col. 14:17-25, 51-65; col. 15:55-61; col. 17:8-17.

dietary supplement" (Dkt. No. 53 at 9) intentionally ignores essential claim terms and is not what the '422 patent teaches. Woodbolt, for its own purposes, asks the Court to now ignore those terms that go to the very heart of the patented invention. The option of rewriting claims, however, particularly to omit claim limitations, is expressly prohibited by the Federal Circuit. *See, e.g., Karsten Mfr. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1384 (Fed. Cir. 2001). The claims at issue can easily be construed given their plain and ordinary meaning as NAI expressly and unambiguously set forth in the prosecution history and considered by the Examiner.[9]

Claim 12 of the '422 patent is drawn to:

> A method to **avoid or delay the onset of muscular fatigue** in a subject, comprising:
>
> a) providing to the subject an amount of an amino acid to blood or blood plasma **effective to increase beta-alanylhistidine dipeptide synthesis in muscle tissue**, wherein said amino acid is at least one of: i) beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide; ii) an ester of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide; or iii) an amide of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide; **and**
>
> b) exposing the muscle tissue to the blood or blood plasma, **whereby the concentration of beta-alanylhistidine is increased in the muscle tissue, thereby avoiding or delaying the onset of muscular fatigue**, wherein the amino acid is provided as a **dietary supplement**, and wherein the subject is not a horse.

---

[9] *See, e.g., Platepass, L.L.C v. Highway Toll Admin., L.L.C.*, C.A. No. 08-3531, Op. at 2 (S.D. Tex. Aug. 30, 2010) (Hughes, J.) ("Usually a court applies the common meaning of words in a claim. When parties dispute the meaning of words, the court must construe them in the context of the entire patent to determine their scope. *See Markman* v. *Westview Instruments, Inc.,* 517 U.S. 370, 388-90 (1996)."); *Accent Packaging, Inc. v. Leggett & Platt, Inc*., C.A. No. 10-1362, Op. at 2 (Hughes, J.) (patent owner "chose its language when it amended its application to narrow its scope."); *Guttman v. Kopykake Enterprises, Inc.*, 302 F.3d 1352, 1359-60 (Fed. Cir. 2002) ("the specification acts as a dictionary when it contains definitions of terms"); *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1379-80 (Fed. Cir. 1998) (arguments made by patentee during prosecution limited the claim scope despite what was in the written description).

(Ex. 2, emphasis added). While Woodbolt improperly broadens the construction of the '422 patent claims for its own purposes to be the "use of beta-alanine as a dietary supplement" (Dkt. No. 53 at 9), the proper reading of claim 12 is "A method to avoid or delay the onset of muscle fatigue and increase the amount of beta-alanylhistidine in the muscles by providing the subject (that is not a horse)[10] as a dietary supplement a large enough amount of the amino acid beta-alanine over a long enough period of time to increase beta-alanylhistidine dipeptide synthesis in the muscle so that the amount of beta-alanylhistidine in the muscle is increased."

1. Woodbolt's Theory And Claim Construction Is Not Supported By Scientific Fact.

The entire premise of Woodbolt's proposed construction is that there is an "inevitable" or "inherent" result that **must** occur when providing **any** amount of beta-alanine to a subject for **any** time period. Woodbolt's premise, however, is contradicted by scientific facts, and the references it relies on do not support its theory.

The patents at issue teach that repeated administration of beta-alanine as a dietary supplement in high amounts over many days can lead to an increase in the levels of dipeptides in the muscles. (Ex. 1 col. 6, l. 62 - col. 7, l. 9; col. 8, l. 66 - col. 9, l. 13; see Examples generally). The dipeptides are the combination of the single amino acid beta-alanine and another amino acid, L-histidine, which together form the dipeptide beta-alanylhistidine. (Ex. 2 col. 2 ll. 21-23). The patents also teach that repeated administration of beta-alanine as a dietary supplement in high amounts over many days can avoid or delay the onset of muscular fatigue. (Ex. 1 col. 6, l. 62 - col. 7, l. 9; col. 8, l. 66 - col. 9, l. 13; see Examples generally). Woodbolt falsely asserts that the "metabolic and physiological processes" related to beta-alanine are "well understood" and that any beta-alanine "will inevitably combine with L-histidine already in the muscle tissue to form

[10] Claim 19 of the '422 patent limits the subject to humans.

the beta-alanyl-histidine dipeptide."[11] (Dkt. No. 53 at 9). This directly contradicts the facts stated by research scientists who worked with supplementation of beta-alanine and these "metabolic and physiological processes." For example, Dr. Mark Tallon wrote in 2006 that:

> Research indicates that right around 3.2 grams of beta-alanine supplementation, daily, can likely impart the desired benefits [of increased levels of dipeptides in human muscles and delaying the onset of muscular fatigue in humans]. However, *this is only achieved after at least three to four weeks of continuous usage*.

(Ex. 9 at 5). Other literature states that "Beta-Alanine takes 1-2 weeks of continued use for it to start increasing performance gains." (Ex. 10 at 18). Given the fact that the information and scientific literature states that continuous dosing over a period of time is needed to overcome the human body's homeostatic controls and obtain an effect, Woodbolt's unsupported and contradictory assertions of inherency are mere attorney argument.

The references cited by Woodbolt (at 9-10 & nn. 11-13) simply do not provide the factual support for its claim construction (or its invalidity arguments, to be addressed further below). For example, both the Asatoor and Gardner references involve ingesting single doses of beta-alanine to determine how the resulting dipeptide carnosine is absorbed. (Ex. 11 at 1-2; Ex. 12 at 2-3). Providing doses continuously over several days is not described in Asatoor and Gardner. This fact is very clear because beta-alanine administration over several days would have eliminated the ability to answer the very questions that Asatoor and Gardner posed.

Asatoor and Gardner also do not address beta-alanine when used as a dietary supplement and do not provide any evidence of amounts effective to increase the function of tissues or delaying the onset of fatigue. Contrary to Woodbolt's assertion, neither Asatoor nor Gardner teach that absorbed beta-alanine will inevitably combine with L-histidine already in the muscle

[11] As discussed above, beta-alanylhistidine dipeptide is a dipeptide that contains beta-alanine in the body; it is also called carnosine. (Ex. 2 col. 2 ll. 21-23).

tissue to form the beta-alanylhistidine dipeptide. Such inevitability would require knowing where in the body beta-alanine is first absorbed or stored before being taken up by the muscle. Further, Gardner discussed the fact that "substantial amounts of [beta]-alanine appeared in the urine", thereby teaching **away** from expecting it to cause the synthesis of the dipeptide. (Ex. 12 at 416). The '422 patent bypasses this issue by teaching repeated daily doses over many days.

Woodbolt also alleges that ingesting beta-alanine "necessarily increases … carnosine in the muscle tissue" based in part on the teachings of Setra. (Dkt. No. 53 at 9-10 & n.13). Setra teaches the use of the **dipeptides** carnosine and other dipeptides (*see, e.g.*, Ex. 13 at 2), but does not even mention the use of beta-alanine as a single amino acid, which Woodbolt admits is the form of beta-alanine covered by the '422 patent. (Dkt. No. 53 at 10). Nor does Setra teach a dietary supplement comprising beta-alanine in an amount effective to increase the function of tissues and delay or avoid the onset of muscular fatigue. Setra states that the benefits of administering the dipeptides (not beta-alanine) are "unpredictable from what is known about the biochemistry and the metabolism of said physiological substances." (Ex. 13 at 2 ll. 23-24). Setra's lack of understanding of the "unpredictable" nature of the dipeptides only adds to the lack of inherency, as well as Setra's inapplicability to the patents-in-suit. Moreover, Setra contradicts Woodbolt's erroneous theory that the metabolic and physiological processes are well understood. Importantly, Serta uses the ingestion of a dipeptide that is known to be absorbed into the human body as an intact dipeptide (*see* Ex. 12 at 419) to increase the amount of that dipeptide in the muscle cells. Woodbolt has proffered no scientific facts or reasons to support the proposition that ingesting the single amino acid beta-alanine that is a **component** of a dipeptide will lead to functionally effective increased amounts of the dipeptide in the muscle cells. For example, the dipeptide also contains the amino acid histidine. By Woodbolt's faulty theory,

feeding histidine would increase the dipeptide synthesis in the muscle cell. There is no evidence that ingesting histidine alone affects dipeptide synthesis in the human body.

In support of its erroneous position on the inevitability of the limitations of the claims of the '422 patent, Woodbolt cites to a rat study by Hama and to Asatoor. (Ex. 11; Ex. 14). Woodbolt's falsely asserted rationale lacks a factual foundation in the cited art and fails to establish inherency. Hama force feeds rats aliquots of beta-alanine and dipeptides through a stomach tube (Ex. 14 at 148), but does not discuss an addition to the human diet in a pill, capsule, tablet, powder, or liquid form, which is not a natural or conventional food. To get the results Hama reports, the rats must be given more than 40 times the dosage equivalent recommended in the patents' examples. (*See* Ex. 14 at 150 Fig. 2). Given the painful effects of parasthesia for a normal dose, individuals would never increase the dosage by as much as in Hama's studies. (*See* Ex. 10 at 17 (describing parasthesia)). Nowhere does Hama teach a dietary supplement in an amount effective in avoiding or delaying the onset of muscular fatigue. As discussed above, Asatoor adds nothing other than what happens in the blood for a single dose of beta-alanine after fasting.[12] Hama does not provide any evidence that beta-alanine force fed into the gut of a rat through a stomach tube effectively increases the function of a tissue to avoid or delay the onset of muscular fatigue. Hama does not provide any evidence that rats are benefited at all by the beta-alanine. In addition, force feeding beta-alanine to rats through a stomach tube is not indicative of normal ingestion. There is no evidence in Hama that would suggest that a dietary supplement of beta-alanine ingested through the mouth, passing naturally through the digestive system into the high pH of the stomach, would result in beta-alanine effectively being

[12] Even the narrow results of Asatoor are in doubt, as indicated by Woodbolt's other reference, Gardner, who points out Asatoor's erroneous assumptions "explains why Asatoor … failed to detect carnosine in plasma." (Ex. 12 at 419).

sequestered by the rat to effectively increase the function of a tissue to avoid or delay the onset of muscular fatigue.

Finally, Woodbolt's own reference, Asatoor, states that "[r]esults obtained in the experimental animal may not necessarily be applicable to man." (Ex. 11 at 254). Indeed, as reported by Serta, supplementing humans with carnosine or the dipeptide anserine will lead to an increase in carnosine in muscle, but Hama teaches something far different. According to Hama, large doses of carnosine or anserine lead to a dramatic reduction of carnosine and serine in the Gastrocnemius muscle. (*See* Ex. 14 at 152-53, Figs. 5-6, dosage H). According to rat studies, high doses of carnosine lead to an almost total loss of anserine. (*See* Ex. 14 at 153, Fig. 6). Given the need of anserine in muscle for buffering, few individuals would risk a total loss of anserine and a loss of creatine to follow the rat as a guide to human usage. According to the rat study, supplements of these dipeptides -- and presumably large supplements of beta-alanine -- lead to a destruction of the buffering system.

Rats are not equivalent to humans and the state of the art was ill-prepared to accept beta-alanine as a dietary supplement based on varying absorption assays that never provided evidence that beta-alanine imparted any increase in the function of tissues or aided in avoiding or delaying the onset of muscular fatigue.

Therefore, Woodbolt did not come forward with undisputed scientific facts supporting its attempt to rewrite the method claims of the '422 patent to only cover providing beta-alanine as a single amino acid to a subject. Its proposed claim construction is premised on bad science and should be rejected.

2. The Construction Of The '422 Patent Claims Must Give Meaning To All Of The Claim Terms.

Giving effect to all of the claim limitations, the Court should construe claim 12 of the '422 patent to mean: "A method to avoid or delay the onset of muscle fatigue and increase the amount of beta-alanylhistidine in the muscles by providing the subject (that is not a horse[13]) as a dietary supplement a large enough amount of the amino acid beta-alanine over a long enough period of time to increase beta-alanylhistidine dipeptide synthesis in the muscle so that the amount of beta-alanylhistidine in the muscle is increased."

As noted, Woodbolt admits that the claims are limited to beta-alanine as a single amino acid and that the amide and ester portion of the claim is not at issue here and need not be construed. (Dkt. No. 53 at 7, 8, 9). "Dietary supplement" should be construed the same way that it is for the '381 patent. (Ex. 15).

The three remaining terms for the Court to construe are: (1) "avoid or delay the onset of muscular fatigue"; (2) "effective to increase beta alanylhistidine dipeptide synthesis in muscle tissue"; and (3) "exposing the muscle tissue to the blood or blood plasma whereby the concentration of beta-alanylhistidine is increased in the muscle tissue."

The first term should be given its plain and ordinary meaning, *i.e.*, to prevent or postpone muscular weariness from exertion.

The second term means that the formation of dipeptides in muscle tissue is increased. The term requires the dipeptide be produced in the muscle and not somewhere else in the body, like the liver.[14] Further, simply providing the beta-alanine amino acid in any amount and for periods

---

[13] Claim 19 of the '422 patent limits the subject to humans.

[14] The liver is the location where the amino acid beta-alanine is synthesized in the body. (Ex. 16, K. Kvalnes-Krick, et al., *Cloning, Sequencing, and Expression of a cDNA Encoding beta-Alanine Synthase from Rat Liver, J. Biol. Chem*, 1993, 268:5686-93).

such as a single dose is insufficient to satisfy the claim. (Ex. 9 at 5; Ex. 10 at 18). Evidence that the blood levels of beta-alanine increase is insufficient to show beta-alanylhistidine synthesis in the muscles because there is no evidence the beta-alanine is taken up by humans in the muscle and no evidence that even if humans took up the beta-alanine, that it is converted to the specific dipeptide. Indeed, in the Gardner reference, all that is shown is that the beta-alanine is taken up into the blood in humans and excreted in the urine. (Ex. 12 at 416).

Moreover, the claim requires that the material supplied in the method be a dietary supplement and that it must be sufficient to increase the amount of dipeptide in the muscle. Thus, the term-which was not construed by Woodbolt-means that the dietary supplement must be provided in a total amount and over a long enough time that "the method raises the level of the dipeptide in human muscle." Accordingly, simply increasing the stored beta-alanine in the muscle cells is not enough, the method must increase muscle synthesis of the beta-alanylhistidine dipeptide.

The term, "exposing the muscle tissue to the blood or blood plasma whereby the concentration of beta-alanylhistidine is increased in the muscle tissue", was also not construed by Woodbolt due to their belief that it was redundant or unneeded. This indicates a fundamental misunderstanding of the limitation on Woodbolt's part. This limitation means that the blood or plasma contacts the muscle in a manner that allows the concentration of the beta-alanine dipeptide to be increased in the muscle tissue. This limitation has meaning and it cannot be simply disregarded.

Taking all parts of the claim together, claim 12 should be construed to cover: "A method to avoid or delay the onset of muscle fatigue and increase the amount of beta-alanylhistidine in the muscles by providing the subject (that is not a horse) a dietary supplement with a large

enough amount of the single amino acid beta-alanine over a long enough period of time to increase beta-alanylhistidine dipeptide synthesis in the muscle so that the amount of beta-alanylhistidine in the muscle is increased." The limitations in the dependent claims can be given their plain and ordinary meaning. Woodbolt has no scientific support for its proposed rewrite of claim 12 of the '422 patents and the relevant dependent claims. NAI respectfully requests that the Court adopt its proposed construction.

C. Woodbolt Erroneously Suggests That The Delaware Court's Prior Claim Construction In A Different Case Involving Other Patents Is Controlling.

Woodbolt takes a presumptive and incorrect position by essentially telling this Court that it must adhere to the Delaware Court's claim construction from another case that did not involve Woodbolt or either of the two patents asserted in this action. (Dkt. No. 53 at 6-7, citing Dkt. No. 53-8). In fact, neither the '381 patent nor the '422 patent had even issued as of the date of the Delaware Court's prior claim construction on other NAI patents.[15] A claim construction ruling in one case is not controlling over the claim construction of another court in another case, even if it involves the same patent. *Morris & Stewart Ltd. P'ship v. Masonite Int'l Corp.*, 401 F. Supp. 2d 692, 697 (E.D. Tex. 2005) (a prior construction of another court is not binding on this court). The Delaware Court's prior claim construction ruling is certainly not the law of the instant case filed in this Texas Court, especially where it involves different parties and patents. Indeed, the patents-in-suit did not issue until long after Judge Sleet issued the claim construction ruling.

Even assuming *arguendo* that it did have some effect on this Court's ability to decide matters for itself, NAI submitted the Delaware Court's claim construction ruling to the Examiner with its First Preliminary Amendment in the then-pending application for the '381 patent to

[15] NAI respectfully suggests that the Delaware Court's decision was erroneous based on the intrinsic evidence and controlling case law, but that case was resolved prior to any appeal.

directly and expressly address the issues raised by the Delaware Court's Order. (Ex. 4; *see also* Ex. 15). Woodbolt's Counterclaim admitted that NAI did so. (Dkt. No. 50 ¶ 16; Dkt. No. 61 ¶ 16). Thus, the Delaware Court's claim construction ruling does not negate NAI's proposed construction of claim 1 of the new '381 patent.

III. THE PATENTS-IN-SUIT ARE NOT INVALID FOR ANTICIPATION OR OBVIOUSNESS.

The patents-in-suit are presumed valid. 35 U.S.C. § 282; *Voda v. Cordis Corp.*, 536 F.3d 1311, 1322 (Fed. Cir. 2008). A defendant must prove invalidity by "clear and convincing evidence" and "a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001). The evidence is to be viewed "in the light most favorable to the nonmoving party and resolves all doubts in its favor." *Id*. (citations omitted). Woodbolt did not meet its burden and thus its motion for summary judgment of invalidity should be denied and NAI's cross motion that the patents are not invalid should be granted.

A. Woodbolt's Five Cited References Do Not Anticipate The Claims Of The '381 And '422 Patents.

1. Woodbolt's Anticipation Argument Is Not Supported By Scientific Facts.

An inventor is entitled to a patent unless "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States…." 35 U.S.C. § 102(b). A patent claim may be invalidated for anticipation only if all of the elements of the claim arranged as in the claim are disclosed within a single prior art reference. *Carella v. Starlight Archery & Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986); *RCA Corp. v. Applied*

Digital Data Sys., Inc., 730 F.2d 1440, 1444 (Fed. Cir. 1984). There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the relevant art. *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991); *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1335 (Fed. Cir. 2002). A convenient way to consider invalidity by anticipation is the "four corners" doctrine, under which invalidity by anticipation requires that each and every limitation of the claimed invention is described either expressly or inherently within the four corners of a single prior art document. *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000). The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993).

Woodbolt has not met its burden of showing that "every element of the several claims of the" '381 and '422 patents were "identically described" in the five references that it asserted. Woodbolt's anticipation argument rests wholly on its erroneous claim construction. A comparison of the properly construed claim terms of the patents-in-suit with the references makes it readily apparent that every limitation of the claims is not found in the asserted prior art. Indeed, Woodbolt's own references provide evidence that the inherent characteristics required for Woodbolt's proffer are not present, much less *necessarily* present. NAI has already demonstrated in § II.B.1 above that Woodbolt lacks a scientific basis for its inherency argument. To establish inherency, Woodbolt must demonstrate that the feature not expressly disclosed by the reference is *necessarily* present in the allegedly anticipating reference. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). The fact that a certain result or characteristic may occur or be present in the art reference is not sufficient to establish the

inherency of that result or characteristic. *Rijckaert*, 9 F.3d at 1534; *In re Oelrich*, 666 F.2d 578, 581-82 (C.C.P.A. 1981). "Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted). Woodbolt has not met its burden to show anticipation by clear and convincing evidence. Its motion should be denied and NAI's cross motion granted.

2. Neither The Asatoor Nor The Gardner Study Is Anticipatory Of Either Patent.

Asatoor and Gardner involve ingestion of beta-alanine as single doses to try to track down how the dipeptide carnosine is absorbed by the intestines, as Woodbolt concedes.[16] (Dkt. No. 53 at 13). Woodbolt asserts the references anticipate because Asatoor and Gardner will always and inevitably achieve the results of the patents. (Dkt. No. 53 at 9-10). Neither reference describes providing the beta-alanine doses many days in a row as required by the science (*see supra* § II.B.1). Nor would Asatoor and Gardner dose over many days because such actions would be inconsistent with their ability to answer the questions posed in their studies.[17] Woodbolt tellingly ignores this flaw in its argument.

Further, Asatoor and Gardner do not address dietary supplements, let alone human dietary supplements, and do not provide any evidence of amounts effective to increase the

[16] Like Gardner, Asatoor conducts tolerance tests in response to beta-alanine. A tolerance test is a medical test in which a bolus of a substance is orally given, preferably after fasting, to determine how the body absorbs, metabolizes and/or excretes the substance. The results from the Gardner and Asatoor studies contradicted one another. For instance, when administered carnosine, Gardner found 14% of carnosine was excreted as a dipeptide and noted Asatoor failed to detect carnosine in the plasma. Gardner noted Asatoor's results "emphasize[] the danger in using plasma measurements as an index of intestinal absorption of intact peptides." (Ex. 12 at 419).

function of tissues or to delay the onset of fatigue. Contrary to Woodbolt's assertion, neither Asatoor nor Gardner disclose that absorbed beta-alanine will inevitably combine with L-histidine already in the muscle tissue to form the beta-alanylhistidine dipeptide. In fact, Woodbolt's references teach that beta-alanine is involved in other metabolic processes. (Ex. 20 ¶ 9). This suggests that beta-alanine in the blood would be sequestered as a neurotransmitter or in calcium signaling, not taken up by the muscles and used for the purposes of the patents-in-suit. (Ex. 20 at ¶ 9). Finally, Gardner discusses the fact that "substantial amounts of [beta]-alanine appeared in the urine," thereby teaching away from expecting it to cause the synthesis of the dipeptide. (Ex. 12 at 416 & Fig. 3C). Similarly, Asatoor points out that many amino acids are rapidly excreted by the kidneys. (Ex. 11 at 253). Neither Asatoor nor Gardner gives any purpose for using beta-alanine and their teachings indicate it would be rapidly excreted when absorbed, suggesting that it would not be useful as a human dietary supplement. At no point do Asatoor or Gardner address, recite, imply or inherently disclose a "human dietary supplement" as required by the '381 and '422 patents. Nor do they expressly or inherently disclose any increase in muscle carnosine delaying the onset of fatigue as required in claim 13 of the '381 patent and claims 12-19 of the '422 patent.

Woodbolt's argument that Asatoor and Gardner are anticipating because ingesting beta-alanine will "inherently" and "necessarily" meet the claim limitations as construed by Woodbolt is unavailing. In the face of the invention disclosed in the '381 and '422 patent specifications and prosecution history, Woodbolt can only speculate or guess as to what the relevant effects on the subject are from receiving a single dose of beta-alanine as part of the absorption test of

---

[17] Gardner and Asatoor are researching how quickly a chemical is absorbed into the blood: giving the chemical over back-to-back days makes absorption of earlier ingested material compete and masks absorption of later ingested material.

Asatoor and Gardner. Further, Woodbolt's assertion that either of these references teach "the absorbed beta-alanine will inevitably combine with L-histidine already in the muscle tissue to form the beta-alanyl-histidine dipeptide" is simply not true, as discussed in § II.B.1.

The '381 and '422 patents disclose that when beta-alanine is given in a sufficiently large amount over long enough a period of time to humans, the amount of the dipeptide in muscle tissues actually increases. (Ex. 1 at col. 6, l. 62-col. 7, l. 9; col. 1, l. 64-col. 2, l. 23; see Examples generally).

The inventors also showed that ingestion of sufficiently large amounts over a sufficient length of time led to increased muscle performance. (Ex. 1, Examples). Consequently, Asatoor and Gardner fail to anticipate claims of the patents-in-suit. Gardner and Asatoor do no more than teach that giving a **single** dose of beta-alanine can increase the beta-alanine concentration in the blood **and** that this is rapidly followed by excretion of beta-alanine by the kidneys. Gardner and Asatoor do not say that beta-alanine in the blood of humans: (1) makes it into the muscle tissue before it is excreted or that it forces an increase in the amount of dipeptide made as required by the invention, (2) that there is an increase in the amount of dipeptide retained in the muscle as required by the invention[18] (*i.e.*, it is not broken down faster than it is created during early periods in the dosing schedule)[19], and (3) that the increased amount of beta-alanine made is sufficient to avoid or delay the onset of muscular fatigue as required by the invention. In the face of the invention disclosed in the '381 and '422 patent specifications, the references are silent as to the effect of a single, isolated dose or why a single isolated dose inevitably leads to the same

[18] The first and second points are relevant to the '422 patent, as the human dietary supplement of the '381 patent only requires that it increase the function of a tissue.

[19] Unlike the patent specification, which indicates the administration occurs over weeks to show effect. (*See*, *e.g.*, Ex. 2 Examples 1-3).

effect as multiple doses over a period of time as taught in the patents. Woodbolt cannot establish any inherent aspects through Gardner and Asatoor. Those references simply are not anticipatory.

3. The Cancer Treatment In The European Patent Application (EP '593) Does Not Anticipate The Patents-In-Suit.

Woodbolt's argument on European reference, Publication No. 0 280 593 ("EP '593") (Ex. 20), can be quickly dispatched. EP '593 teaches the use of beta-alanine as a pharmaceutical composition to treat cancer. As discussed above, the patents-in-suit disclaimed such pharmaceutical uses as being within the scope of the claims. Further, at no point does EP '593 address, recite or imply a "human dietary supplement" or its use found in the '381 and '422 patents. EP '593 states that beta-alanine is useful in treating cancer. (Ex. 20 ¶¶ 11, 22). EP '593 does not demonstrate any increase in the function of tissues or to avoid muscle fatigue after consumption of beta-alanine by cancer patients. EP '593 discloses a pharmaceutical use as a cancer treatment, not a dietary supplement, and the inventive purpose of the '381 and '422 patents to increase function, increase the levels of carnosine in the muscles, and delay the onset of muscle fatigue are not found in the reference. One of ordinary skill in the art would not contemplate cancer treatment as a method to increase muscle carnosine levels and as a method of delaying muscle fatigue. EP '593 does not anticipate.

4. The Two Food Flavors and Aroma References Do Not Anticipate.

The Pittet and Wilson references (Exs. 21, 22), directed to processes for imparting flavors and aromas to food, do not anticipate the '381 patent. As shown above, the prosecution history of the patents-in-suit specifically disclaimed food compositions as human dietary supplements and disclaimed the subject matter of the references and arguments that relate to beef, pork, chicken, meat extract supplements and predigested meat/protein supplement.

At no point does either Pittet or Wilson address, recite or imply it is teaching a "human dietary supplement" within the scope of the '381 patent as properly construed. Pittet discloses a flavoring composition containing beta-alanine that produces a solid composition with a beef flavor (Ex. 21, Example XII). Wilson discloses compositions that contain beta-alanine and chicken aroma (Ex. 22, Examples I and II). Neither Pittet nor Wilson disclose any increase in the function of tissues after consumption. Nor do they describe the multiple daily dosing at high beta-alanine levels that scientists and the '381 patent describe to achieve increased carnosine levels in muscle and delay the onset of fatigue. Woodbolt can only speculate or guess as to what the effects would be for consuming Pittet's and Wilson's flavored, natural and conventional foodstuff. The references simply do not render the claims of the '381 patent invalid.

B. The Patents-In-Suit Are Not Obvious.

Woodbolt argues that the patents-in-suit are invalid as obvious based on the Setra reference combined with other references, only one of which was discussed in Woodbolt's motion, Asatoor.[20] Under § 103(a), a patent may be found invalid only "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The determination of obviousness is a legal conclusion based on underlying factual considerations. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966). These factual inquiries include: (1) the scope and content of the prior art; (2) the differences between the prior art and claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) objective evidence of non-obviousness (*i.e.*, secondary

[20] Woodbolt's brief does not raise obviousness arguments as to the '422 patent. Therefore, any such arguments at the summary judgment stage are waived and the claims must be found valid.

considerations, such as commercial success and widespread copying). *Id.*; *Brown & Williamson Tobacco Corp. v. Philip Morris Inc*., 229 F.3d 1120, 1124 (Fed. Cir. 2000).

Woodbolt's reliance on Setra to try to show obviousness is unavailing. Setra teaches the use of dipeptides (*e.g.*, carnosine). Setra states that "in addition to carnosine, other dipeptides containing histidine imidazole ring can be used . . ." (Ex. 13 at 2). Woodbolt admits that the patents-in-suit are expressly directed to beta-alanine as a **single** amino acid and not a dipeptide. (Dkt. No. 53 at 8). It is undisputed that NAI explicitly disclaimed any subject matter related to dipeptides in the prosecution history of the '381 and the '422 patents. (Ex. 4 at 4-6; Ex. 15 at 5-7). Thus, Setra uses the dipeptide carnosine and other dipeptides, and does not use beta-alanine as claimed in the '381 patent

Setra's deficiencies are not remedied by Asatoor. Asatoor does not teach a "human dietary supplement" within the scope of the claims in the '381 patent and does not teach daily dosing with beta-alanine in large amounts as taught by the patents-in-suit and scientists in the field to obtain functionally effective improvements and delaying the onset of fatigue (*e.g.*, Ex. 1 claim 13 and § II.A.1, *supra*). Asatoor's simple absorption assays were discussed extensively above. Moreover, Asatoor was published about 21 years prior to Setra and Asatoor did not provide sufficient underlying rationale for Setra to rely on or claim a human dietary supplement as found in the '381 patent. The Supreme Court has pointed out the "import[ance] to identify a **reason** that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (emphasis added). The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *Rijckaert*, 9 F.3d at 1534; *Oelrich*, 666 F.2d at 581-82. Woodbolt does not provide a reason to

combine the reference and Woodbolt's cited art does not provide the necessary teaching, expressly or inherently, for one of ordinary skill in the art to ascertain or perform the '381 patent's invention.

Woodbolt wants the Court to believe that one of ordinary skill in the art would combine the two references, but fails to tell the Court that Asatoor uses the beta-alanine for an entirely different purpose compared to that of Setra. All Asatoor does is get the amino acid into the bloodstream. Asatoor does not show that the amino acid gets into the muscle and increases the function of the muscle tissue. As described by the scientists in the field, to get the amino acid to increase the function of the muscle tissue, weeks of ingestion of the amino acid are necessary. (Ex. 9 at 5). Neither Setra nor Asatoor teach that key element of the claims of the '381 patent. Moreover, Gardner discusses the fact that "substantial amounts of [beta]-alanine appeared in the urine," thereby teaching away from expecting it to cause synthesis of the dipeptide or to increase the function of tissue. (Ex. 12 at 416). Importantly, Setra uses the ingestion of a dipeptide that is known to be absorbed into the human body as a dipeptide to increase the amount of that dipeptide in the muscle cells and to increase the function of tissue. (*See* Ex. 12 at 419). There is no scientific reason to believe that feeding one of the components of that dipeptide, beta-alanine, will lead to effective increased amounts of the dipeptide in the muscle cells or an increase in the function of tissue. After all, the dipeptide also contains the amino acid histidine and contains carbon and nitrogen -- feeding histidine or carbon or nitrogen to a human does not increase the dipeptide synthesis in the muscle cell.[21] Thus, there is no reason to combine Setra and Asatoor, but even if there was, it would not result in the invention claimed in the '381 patent.

[21] While carbon and nitrogen are components of carnosine, no one would argue eating charcoal (a carbon source) and nitrogen fertilizer (a nitrogen source) will increase formation of the dipeptide carnosine in the muscle.

Finally, under the U.S. Supreme Court's holding in *KSR Int'l*, 127 S. Ct. 1727, the courts are to look not only at the scope and content of the prior art, but also at "secondary considerations" of non-obviousness to determine whether an invention is an obvious combination. Among the secondary considerations are industry recognition and awards and commercial success.

On August 3, 2011, the International Society of Sports Nutrition ("ISSN") granted a lifetime achievement award to Dr. Roger Harris, a named inventor on the patents-in-suit, in part for his contribution to demonstrating the importance of beta-alanine supplementation in elevating carnosine in human muscle. (Ex. 24 at 1) In presenting the award, the ISSN President described Dr. Harris' contribution as a key development in sports nutrition. (Ex. 24 at 1). This was the first such award made in the history of the ISSN. This recognition of Dr. Harris is an indicia of non-obviousness of the patents-in-suit. Further, the patented inventions have been a commercial success, another indicia of non-obviousness. For example, during the nine months ended March 31, 2012, NAI's royalty revenue from sales of CarnoSyn® beta-alanine by its authorized distributor totaled $4.1 million. (Dkt. No. 14-2 ¶ 15; C.A. No. 12-1388, Dkt. No. 14, Ex. 22 at 15).

Accordingly, the patents-in-suit are not invalid under § 103.

C. Woodbolt's Priority Argument Is Wrong As A Matter Of Law And NAI's Own '596 Patent Does Not Invalidate The '381 And '422 Patents.

Woodbolt's argument that NAI's own patent, No. 5,965,596 ("the '596 patent"), anticipates the '381 and '422 patents due to an alleged "break" in priority is nothing more than a red herring. The patent statute provides that a later-filed patent application can receive the benefit of the priority of an earlier filed application, provided that three prerequisites are met. 35 U.S.C. § 120. Woodbolt admits in its motion that the first four applications filed by the inventors

fully complied with § 120 and that those applications had the priority of the first application. (Dkt. No. 53 at 16-17). While the fourth application was pending, the inventors filed their fifth application, claiming priority to the fourth application. (Ex. 17). Woodbolt admits that when this fifth application was filed, it met all of the requirements of § 120 to receive the benefit of the earlier priority. (Dkt. No. 53 at 17). While the fifth application was pending, the inventors filed a sixth application, which properly claimed priority to the fifth application. (Ex. 18). After the sixth application had already been filed and was pending before the PTO, the inventors amended the fifth application to change the fifth application's claimed priority. (Ex. 19). Woodbolt again concedes that the '381 and '422 patents "contain purported claims to the U.S. priority of the earliest application of the family, filed on August 12, 1997, under 35 U.S.C. § 120." (Dkt. No. 53 at 16). Woodbolt asserts in its motion that the amendment of the fifth application's priority must somehow relate back in time, *nunc pro tunc*, to also change the properly claimed priority of the sixth application. Woodbolt's assertion is incorrect under 35 U.S.C. § 120. There is no support in the statute or other legal authority for Woodbolt's proposition. As such its priority argument cannot prevail and must be rejected.

Section 120 proves NAI's position. "The first sentence of § 120 permits an application to claim the benefit of an earlier filing date, such that the application is treated as having been effectively filed on the earlier date." *Loughlin v. Ling*, 684 F.3d 1289, 1294 (Fed. Cir. 2012). Section 120 provides that:

> An application for patent for an invention disclosed in the manner provided by section 112(a) (other than the requirement to disclose the best mode) in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first

> application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application. No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director.

Specifically, § 120 has three prongs that must be satisfied for a later-filed application to claim the benefit of the filing date of another patent application. "Provided the criteria in § 120 are met, applications ***'shall,'*** without exception, receive the benefit of the earlier filing date." *Loughlin*, 684 F.3d at 1293 (emphasis added). The three prongs are: (1) satisfaction of the requirements of 35 U.S.C. § 112 1st ¶, *i.e.*, enablement, written description and best mode; (2) the later application must be **co-pending** (*i.e*., overlapping in time) with an earlier application at the time when the later application is filed; and (3) the application must contain or be amended to contain a **specific reference** to the earlier filed application.[22] Woodbolt's motion does not contest that NAI's applications met the first statutory prong and it has thus waived any contrary argument. Thus, only the second and third prongs are before the Court for decision. Each patent in the priority chain of the '381 and '422 patents satisfies the second and third prongs of § 120, and thus, each is accorded the priority benefit of NAI's first patent application.

---

[22] Commentary by one of the authors of 35 U.S.C. § 120 also supports NAI's analysis. Only three conditions were necessary to obtain the priority date of a prior application: (1) the invention must be disclosed sufficiently under the 1st ¶ of § 112, (2) the second application must be at least transiently **co-pending** with the first application, and (3) the second application must contain specific reference to the first application. P.J. Federico, COMMENTARY ON THE NEW ACT, 1954 Edition of the U.S. Code Ann., reprinted in 75 J. Pat. & Trademark Off. Soc'y 161 (1993) ("Commentary"). (Dkt. No. 43 Ex. J). "When these three conditions obtain[,] the second application is entitled to have the same effect as though filed on the same date that the first application was filed, with respect to an invention disclosed in both applications." *Id.* at 192-93. "Co-pendency" refers to the requirement that the second application must be "filed before the patenting or abandonment of or termination of proceedings on the first application." *Id*. at 193.

The following chart summarizes the history of NAI's relevant beta-alanine patent portfolio, including the order in which applications were filed, the application numbers and dates filed, and the patent numbers and their issue dates, where applicable:

Woodbolt's Application Nomenclature	Application No.	Filed	Issued	Patent No.
Seventh	13,215,073	Aug. 22, 2011	Nov. 29, 2011	8,067,381
Intermediate	12/806,356	Aug. 10, 2010	Mar. 6, 2012	8,129,422
Sixth	12/231,240	Aug. 29, 2008	Nov. 2, 2010	7,825,084
Fifth	10/717,217	Nov. 18, 2003	Mar. 17, 2009	7,504,376
Provisional	60/462,238	Apr. 10, 2003		
Fourth	10/209,169	July 30, 2002	Jan. 20, 2004	6,680,294
Third	09/757,782	Jan. 9, 2001	July 30, 2002	6,426,361
Second	09/318,530	May 25, 1999	Jan. 9, 2001	6,172,098
First	08/909,513	Aug. 12, 1997	Oct. 12, 1999	5,965,596
	UK 9621914.2	Oct. 21, 1996		
	UK 9616910.7	Aug. 12, 1996		

(Dkt. No. 43 Exs. A-I). The chart illustrates that each application was co-pending – overlapping – with an earlier-filed application as required under § 120 at the time the priority claim was made at the PTO.

Woodbolt's motion specifically admits that NAI's first, second, third and fourth applications met the three prongs of § 120 and those applications are entitled to the effective filing date of the first application, August 12, 1997 (which is entitled to the benefit of the 1996 filing date). (Dkt. No. 53 at 17).

It is undisputed that the inventors filed the fifth application, No. 10/717,217, on November 18, 2003, properly claiming the priority of (1) the fourth application and (2) a provisional application filed on April 10, 2003. (Ex. 17). Woodbolt clearly admits that "[w]hen the Fifth Application was filed, it too **met these three [§ 120] criteria**." (Dkt. No. 53 at 17, emphasis added; *see also id.* at 21). On August 29, 2008, the inventors filed the sixth application, No. 12/231,240, properly claiming benefit of the fifth application. While the sixth application was pending, on August 10, 2010, the inventors filed the "intermediate" application, No.

12/806,356, claiming benefit of the priority of that sixth application. Finally, on August 22, 2011, while the intermediate application was pending, the inventors filed the seventh application, No. 13,215,073, which claimed priority based on the intermediate application. The intermediate application and the seventh application matured into the '422 and '381 patents, respectively. These facts cannot be disputed. Thus, for each patent in NAI's family, the later and earlier applications were properly **co-pending** and the later application **specifically referred** to the earlier application. NAI fully complied with the requirements of § 120 necessary to obtain the benefit of the earliest priority.

Woodbolt's argument is limited to one event in this chain. Recall that the inventors filed the fifth application on November 18, 2003 and the sixth application, which claimed priority to the fifth application, on August 29, 2008. The fifth and sixth applications were co-pending. On September 2, 2008, while the fifth and sixth applications were co-pending, the inventors amended the fifth application to change the priority date of the application. (Exs. 17-19). Woodbolt tries to argue that the amendment to the fifth application reaches back in time such that it renders the proper priority claim of the sixth application a nullity. In essence, Woodbolt is trying to convince the Court that by amending the priority of the fifth application on September 2, 2008, (thus, it no longer claims the priority it did on August 29, 2008), the amendment has a collateral effect on the August 29, 2008 priority date of the sixth application. Woodbolt is wrong. The argument is erroneous because, under § 120, the priority claim for the sixth application was complete and accurate at the time it was filed on August 29, 2008. The fifth application was not amended until September 2, 2008, and that amendment **cannot** relate back to change or otherwise affect the August 29, 2008 priority claim of the sixth application. It is undisputed that

the sixth application was filed on August 29, 2008, **before** the amendment to priority of the fifth application filed on September 2, 2008.

Woodbolt's argument is contrary to the plain meaning of § 120 and its motion was devoid of any judicial precedent. Woodbolt will not find any, because the priority claim is determined as of the date of filing the later application that claims priority to the earlier application.[23] Given Woodbolt's admission that the first through fifth applications properly claimed priority under § 120 at the time the sixth application was filed, its unsupported contention that there was a break in priority invites judicial error.

Finally, Woodbolt's argument (at 19-21) that NAI made misrepresentations to the PTO in claiming priority is specious. Woodbolt's position flies in the face of its own admission and necessarily rests on its unsupported legal theory that a subsequent amendment to an application's priority claim must be deemed to be retroactive and would apply to a different application that had already been accepted for filing by the PTO with a proper priority claim. NAI debunked that theory above. The inventors' statements to the PTO in the applications for the patents-in-suit – that the sixth application is a continuation of the fifth application, **and** that sixth application is a continuation-in-part of the fourth application – were true when they were made and they **remain true** to this day. As such, NAI properly claimed priority and there could be no misrepresentation.

---

[23] An application's sufficiency for the first prong of the § 120 test, written description under § 112 1st ¶, "must be judged as of its filing date." *In re Hogan*, 559 F.2d 595, 604 (C.C.P.A. 1977) (internal quotations omitted). "That principle applies equally to the PTO with respect to a continuing application entitled under § 120 to the benefit of an earlier filing date." *Id.* Other cases confirm that a § 120 priority claim is proper if a later application references an earlier filed application. *Encyclopaedia Britannica, Inc. v. Alpine Elecs. of Am., Inc.,* 643 F. Supp. 2d 874 (S.D. Tex. 2009) (holding a patent application cannot claim the priority benefit of another if it never referenced the application with the earlier priority benefit); *Struthers Patent Corp. v. Nestle Co*., 558 F. Supp. 747 (D.N.J. 1981) (holding priority claim is proper if an application references an earlier filed application); *Clover Club Foods v. Gottschalk*, 1973 U.S. Dist. LEXIS 14393, *5 (C.D. Cal. May 21, 1973) (accord).

Accordingly, Woodbolt's priority-based argument is contrary to law and the patents-in-suit are entitled to the 1996 priority date. As such, NAI's '596 patent cannot be invalidating prior art.

D. Woodbolt's Assertion That The PTO's Preliminary Action In An *Inter Partes* Reexamination Proceeding Should Be Considered Binding On This Court Is Improper And Incorrect.

Woodbolt improperly attempts to bootstrap in statements made by the PTO reexamination examiner in her preliminary office action as if they are controlling on this Court. If asked, both Woodbolt and NAI's counsel would agree that similar office actions are issued in other reexamination proceedings – approximately 95% of the time. (Ex. 23). How Woodbolt can tell this Court with a straight face that something that occurs in 95% of all reexamination proceedings at the PTO is somehow uniquely special in this case and therefore, should be given extra weight, is beyond logic. Woodbolt cannot tell this Court to give any persuasive, let alone binding, authority to the PTO's preliminary action on Woodbolt's reexamination request.

Woodbolt erroneously inflates the significance of the PTO's action granting its request for reexamination, arguing that it mandates the Court to find the patents invalid. To the contrary, this is nothing more than a preliminary administrative action taken by the PTO that has no estoppel effect on this Court. The Federal Circuit has plainly ruled that "the grant by the examiner of a request for reexamination is not probative of unpatentability." *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1584 (Fed. Cir. 1996). Nor does that action "establish a likelihood of patent invalidity." *Id*. While Woodbolt would have the Court believe that the reexamination order indicates that the '381 and '422 patents will ultimately be cancelled, the Federal Circuit has recognized that invalidation as a result of the reexamination proceeding is statistically low. *Id*. In fact, the PTO reports that while 94% of requests for *inter partes* reexamination are granted, only 10% of those reexaminations actually resulted in the issuance of

certificates with all claims canceled or disclaimed. (Ex. 23). The fact that the PTO granted Woodbolt's request is meaningless in predicting the eventual outcome of the reexamination or in this Court's consideration of the summary judgment issues here.

Further, the PTO's issuance of its First Office Action rejecting claims is non-binding and unpersuasive to this Court's determination of validity on summary judgment. "[J]ust like its name implies, the First Office Action is only a *preliminary* determination by the USPTO – it is not a 'final' action, and the examiner could still change his decision or completely reverse it before issuing the final action." *Presidio Components Inc. v. Am. Tech. Ceramics Corp.*, 723 F. Supp. 2d 1284, 1301 (S.D. Cal. 2010) (emphasis in original). "Accordingly, any such determination is *not* persuasive evidence of anticipation or obviousness." *Id.* (emphasis in original). Further, "[e]ven if [the office action] were a final rejection, until the patentee addresses the rejections with argument or claim amendments and the reexamined patent issues, the prosecution history is incomplete and estoppel has yet to be determined." *Cimcore Corp. v. Faro Techs., Inc.*, 2007 WL 935665 at *2 (S.D. Cal. March 12, 2007).

The PTO took its initial action having had the benefit of only Woodbolt's reexamination request. NAI has until September 26 to respond to the First Office Action. (Dkt. 53 Ex. 4 at 27). Woodbolt will then have thirty days to comment on NAI's response. (*Id.*). Upon considering the parties' full responses and comments, the PTO examiner will withdraw her rejection, modify her rejection, or issue a final office action, which is subject to additional comments by the parties, followed by potential appeal of the decision. *See* 37 C.F.R. 1.951; 35 U.S.C. § 315. There is no deadline for the PTO to act once all of the parties have completed their submissions. The process can be expected to last **years**. Even upon issuance of a final office action, a court must decide validity of a patent based on the "prior art adduced in the proceeding before the court." *Quad*

Envtl. Techs. Corp. v. Union Sanitary Dist., 946 F.2d 870, 875-76 (Fed. Cir. 1991). The Federal Circuit confirmed that "courts are the final arbiter of patent validity and, although courts may take cognizance of, and benefit from, the proceedings before the patent examiner, the question is ultimately for the courts to decide, without deference to the rulings of the patent examiner." *Id.* at 876.

Thus, Woodbolt ignores the fact that the PTO has not yet considered NAI's response and its non-final first office action has no probative or even persuasive value on this Court's determination of the parties' summary judgment motions.

CONCLUSION

For all the foregoing reasons, the Court should deny Woodbolt's summary judgment and grant NAI's cross motion.

Richard J. Oparil
S.D. Texas Bar No. 30422
Kevin M. Bell
Scott Chambers, Ph.D.
Lacy Kolo, Ph.D.
PATTON BOGGS LLP
2550 M Street, NW
Washington, DC 20037
(202) 457-6000
roparil@pattonboggs.com

/s/ Richard J. Oparil
Glenn A. Ballard, Jr.
State Bar No. 01650200
BRACEWELL & GUILIANI
South Tower Pennzoil Place
711 Louisiana, Suite 2300
(713) 223-2300
(713) 221-1212 (fax)

Caroline Cook Maxwell
State Bar No. 24055341
S.D. Texas Bar No. 927197
PATTON BOGGS LLP
2000 McKinney Avenue, Suite 1700
Dallas, TX 75201
(214) 758-1500

Attorneys for Plaintiff
Natural Alternatives International, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on August 17, 2012, a copy of the foregoing was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

/s/ Richard J. Oparil
Richard J. Oparil